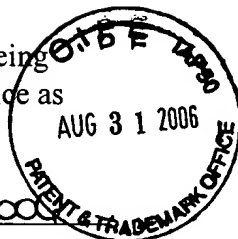


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SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT
Examining Group 1617
Patent Application
Docket No. MET-037CXT
Serial No. 09/900,364

Frank C. Eisenschenk

Frank C. Eisenschenk, Ph.D., Patent Attorney

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Leonard M. Williams
Art Unit : 1617
Applicants : Paul D. van Poelje, Mark D. Erion, Toshihiko Fujiwara
Serial No. : 09/900,364
Filed : July 5, 2001
Conf. No. : 7049
For : Combination of FBPase Inhibitors and Antidiabetic Agents Useful for the Treatment of Diabetes

Mail Stop Amendment
Commissioner for Patents
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Alexandria, VA 22313

SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT UNDER 37 CFR §§1.97 AND 1.98

Sir:

In accordance with 37 CFR §1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. A copy of each cited reference is enclosed. However, Applicants have not submitted copies of the U.S. patents cited on attached Form PTO/SB/08 pursuant to 37 CFR 1.98(a)(2)(ii).

It is respectfully requested that the references cited on the attached form PTO/SB/08 be considered in the examination of the subject application and that their consideration be made of record.

J:\MET\037CXT\PTO-Misc\IDS.suppl.doc\DNB/sl

This information is being submitted subsequent to the later of three months after the filing date of the present application or the mailing of the first Office Action on the merits, but before the mailing of a final action or the notice of allowance. Please charge the fee of \$180.00 to Deposit Account No. 19-0065.

Applicants respectfully assert that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

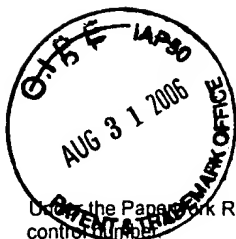
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Gainesville, FL 32614-2950

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Attachments: Form PTO/SB/08; copies of references cited therein.



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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Complete if Known

Application Number	09/900,364
Filing Date	July 5, 2001
First Named Inventor	Paul D. van Poelje
Art Unit	1617
Examiner Name	Leonard M. Williams
Attorney Docket Number	MET-037CXT

Sheet 1 of 6

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code* (if known)			
	U1	US-4,968,790	11-06-1990	DeVries et al.	All
	U2	US-5,728,704	03-17-1998	Mylari et al.	All
	U3	US-4,278,791	07-14-1981	Botta et al.	All
	U4	US-5,342,850	08-30-1994	Ohnota et al.	All
	U5	US-6,147,101	11-14-2000	Maeda et al.	All
	U6	US-			
	U7	US-			
	U8	US-			
	U9	US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T*
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
	F1	EP 0354322	06-16-1989	American Cyanamid Company	All	
	F2	WO 99/45016	09-10-1999	Metabasis Therapeutics, Inc.	All	
	F3	WO 90/08155	07-26-1990	Board of Regents- University of Texas	All	
	F4	WO 90/10636	09-20-1990	Board of Regents- University of Texas	All	
	F5					
	F6					
	F7					

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	R1	AZEN, S.P. <i>et al.</i> , "TRIPOD (Troglitazone In the Prevention of Diabetes): A Randomized, Placebo-Controlled Trial of Troglitazone in Women with Prior Gestational Diabetes Mellitus," <i>Controlled Clinical Trials</i> , Vol. 19, Issue 2, Pages 217-231, Elsevier B.V. (April 1998).	
	R2	CHIASOON, J.-L. <i>et al.</i> , "Acarbose for the prevention of Type 2 diabetes, hypertension and cardiovascular disease in subjects with impaired glucose tolerance: facts and interpretations concerning the critical analysis of the STOP-NIDDM Trial data," <i>Diabetologia</i> , 47: 969-975, Springer-Verlag (2004).	
	R3	DELORME, S. <i>et al.</i> , "Acarbose in the prevention of cardiovascular disease in subjects with impaired glucose tolerance and type 2 diabetes mellitus," <i>Current Opinion in Pharmacology</i> , 5:184-189, Elsevier (2005).	
	R4	DICKSON, J.K. <i>et al.</i> , "Orally Active Squalene Synthase Inhibitors: Bis((acyloxy)alkyl) Prodrugs of the α -Phosphonosulfonic Acid Moiety" <i>J. Med. Chem.</i> 39: 661-664 American Chemical Society (1996).	
	R5	EGRON, D. <i>et al.</i> , "Synthesis and Anti-HIV Activity of Some S-Acyl-2-Thioethyl (Sate) Phosphoramidate Derivatives of 3'-Azido-2',3'Dideoxythymidine" <i>Nucleosides & Nucleotides</i> 18(4&5): 981-982 Marcel Dekker, Inc. (1999).	
	R6	ERION, M.D. <i>et al.</i> , "Computer-Assisted Scanning of Ligand Interactions: Analysis of the Fructose 1,6-Bisphosphatase-AMP Complex Using Free Energy Calculations" <i>J. Am. Chem. Soc.</i> 122:6114-6115 American Chemical Society (2000).	
	R7	ERION, M.D. and REDDY, M.R. "Ligand Interaction Scanning Using Free Energy Calculations" <i>Free Energy Calculations in Rational Drug Design</i> , Chapter 11, 225-241 Springer-Verlag (2001).	
	R8	ERION, M.D. <i>et al.</i> , "MB06322 (CS-917): A Potent and Selective Inhibitor of Fructose 1,6-Bisphosphatase for Controlling Gluconeogenesis in Type 2 Diabetes" <i>PNAS</i> 102(22): 7970-7975 (May 2005).	
	R9	FISHER, J.S. <i>et al.</i> , "Glucose transport rate and glycogen synthase activity both limit skeletal muscle glycogen accumulation," <i>The American Journal of Physiology Endocrinol. Metab.</i> , Vol. 282, pp. E1214-E1221, American Physiological Society (June 2002).	
	R10	FUJIWARA, T. <i>et al.</i> , "Suppression of Hepatic Gluconeogenesis in Long-Term Troglitazone Treated Diabetic KK and C57BL/KsJ-db/db Mice" <i>Metabolism</i> 44(4): 486-490 (April 1995).	

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Signature

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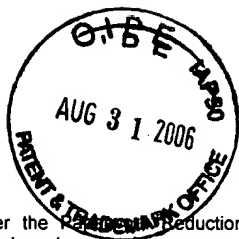
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Application Number	09/900,364
Filing Date	July 5, 2001
First Named Inventor	Paul D. van Poelje
Group Art Unit	1617
Examiner Name	Leonard M. Williams
Attorney Docket Number	MET-037CXT

Sheet 3 of 6

NON PATENT LITERATURE DOCUMENTS

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	R11	GIDH-JAIN, M. <i>et al.</i> , "The Allosteric Site of Human Liver Fructose-1,6-Bisphosphatase" <i>Journal of Biological Chemistry</i> , 269(44): 27732-27738 The American Society for Biochemistry and Molecular Biology, Inc. (1994).	
	R12	HOLMAN, R.R. "Assessing the potential for α -glucosidase inhibitors in prediabetic states," <i>Diabetes Research and Clinical Practice</i> , Vol. 40, Supp. 1, Pages 21-25, Elsevier Ireland Ltd. (July 1998).	
	R13	HOWARD, G. <i>et al.</i> , "Insulin Sensitivity and Atherosclerosis" <i>Circulation</i> 93(10): 1809-1817 (May 15, 1996).	
	R14	HULLEY, S. <i>et al.</i> , "Randomized Trial of Estrogen Plus Progestin for Secondary Prevention of Coronary Heart Disease in Postmenopausal Women," <i>J. of Am. Medical Assoc.</i> , Vol. 280, No. 7, pp. 605-613 (August 19, 1998).	
	R15	LINK, J.T. <i>et al.</i> , "Pharmacological regulation of hepatic glucose production," <i>Curr. Opin. Investig. Drugs</i> , 4(4):421-9, (April 2003).	
	R16	MAGGS, D.G. <i>et al.</i> , "Metabolic Effects of Troglitazone Monotherapy in Type 2 Diabetes Mellitus" <i>Annals of Internal Medicine</i> 128(3):176-185 American College of Physicians (February 1, 1998).	
	R17	MARYANOFF, B. E. <i>et al.</i> , "Stereoselective Synthesis and Biological Activity of β - and α -D-Arabinose 1,5-Diphosphate: Analogues of a Potent Metabolic Regulator" <i>J. Am. Chem. Soc.</i> 106:7851-7853 (1984).	
	R18	OKUNO, A. <i>et al.</i> , "CS-917, a Fructose 1,6-Bisphosphatase (FBPase) Inhibitor, Suppresses Gluconeogenesis In Vitro and In Vivo by a Different Mechanism than Metformin" poster presented at The American Diabetes Association 66 th Scientific Session, Washington, DC (June 2006).	
	R19	PICKAVANCE, L. <i>et al.</i> , "The Development of Overt Diabetes in Young Zucker Diabetic Fatty (ZDF) Rats and the Effects of Chronic MCC-555 Treatment" <i>British Journal of Pharmacology</i> , 125: 767-770 Stockton Press (1998).	
	R20	POTTER, S.C. <i>et al.</i> , "Effect of MB06322, a Potent and Selective Inhibitor of Fructose 1,6-Bisphosphatase, on Gluconeogenesis in the ZDF Rat as Assessed by the Deuterated Water Technique" <i>DIAEAZ</i> 52(2): A364, Journal of the American Diabetes Association Abstract No. 1516-P, American Diabetes Association (June 2004).	

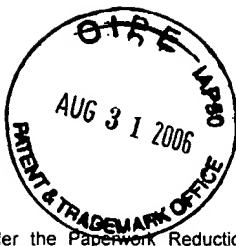
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		Application Number	09/900,364
		Filing Date	July 5, 2001
		First Named Inventor	Paul D. van Poelje
		Group Art Unit	1617
		Examiner Name	Leonard M. Williams
		Attorney Docket Number	MET-037CXT
Sheet	4	of	6

NON PATENT LITERATURE DOCUMENTS			
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	R21	POTTER, S.C. "Evidence Implicating Gluconeogenesis Inhibition as the Mechanism by Which MB06322 Lowers Blood Glucose In Vivo" <i>DIAEAZ</i> 52(2): A364, Journal of the American Diabetes Association Abstract No. 1517-P, American Diabetes Association (June 2004).	
	R22	PRISANT, L.M. "Preventing Type II Diabetes Mellitus," <i>J. Clin. Pharmacol.</i> , 44:406-413, American College of Clinical Pharmacology (2004).	
	R23	REDDY, M.R. and ERION, M.D. "Computer Aided Drug Design Strategies Used in the Discovery of Fructose 1,6-Bisphosphatase Inhibitors" <i>Current Pharmaceutical Design</i> 11: 283-294 Bentham Science Publishers Ltd. (2005).	
	R24	REDDY, K.R. <i>et al.</i> , "Discovery of 2-Aminopyridine Inhibitors of FBPase" abstract for the 230 th National American Chemical Society (ACS) Meeting, Washington, DC, Aug./Sept. 2005, ACSMEDI Program and Abstract Book Archives, pp. 197-198, MEDI 323, obtained from http://oasys.acs.org/acs/230nm/medi/staff/separates.cgi 8/8/2005.	
	R25	REDDY, M.R. and ERION, M.D. "Fructose 1,6-Bisphosphatase: Use of Free Energy Calculations in the Design and Optimization of AMP Mimetics" <i>Free Energy Calculations in Rational Drug Design</i> , Chapter 14, 285-297 Springer-Verlag (2001).	
	R26	RIDDLE, M.C. "New Tactics for Type 2 Diabetes: Regimens Based on Intermediate-Acting Insulin Taken at Bedtime" <i>The Lancet</i> 192-195 (January 26, 1985).	
	R27	SATHYAPRAKASH, R. <i>et al.</i> , "Preventing Diabetes by Treating Aspects of the Metabolic Syndrome," <i>Current Diabetes Reports</i> , 2:416-422, Current Science Inc. (2002).	
	R28	SCHEEN, A.J. and LEFEBVRE, P.J. "Oral Antidiabetic Agents A Guide to Selection" <i>Drugs</i> 55(2):225-236 Adis International Limited (February 1998).	
	R29	SREENAN, S. <i>et al.</i> , "Prevention of Hyperglycemia in the Zucker Diabetic Fatty Rat by Treatment with Metformin or Troglitazone" <i>Am. J. Physiol.</i> 271 (<i>Endocrinol. Metab.</i> 34): E742-E747 American Physiological Society (1996).	
	R30	SRIVASTVA, D.N. and FARQUHAR, D. "Bioreversible Phosphate Protective Groups: Synthesis and Stability of Model Acyloxymethyl Phosphates" <i>Bioorganic Chemistry</i> 12: 118-129 Academic Press, Inc. (1984).	

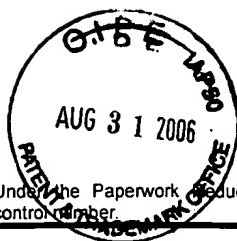
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Sheet 5 of 6

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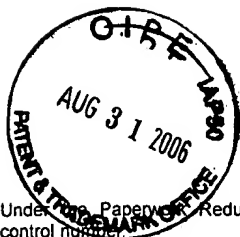
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	R31	TORLONE, E. <i>et al.</i> , "Improved Insulin Action and Glycemic Control After Long-Term Angiotensin-Converting Enzyme Inhibition in Subjects with Arterial Hypertension and Type II Diabetes" <i>Diabetes Care</i> 16(10):1347-1355 (October 1993).	
	R32	TORRES, T. <i>et al.</i> , "Inhibition of glycogen phosphorylase suppresses basal and glucagon-induced glucose production and increases glucose uptake in the liver of conscious dogs" (Integrated Physiology—Liver 1484-P), <i>Diabetes</i> , Vol. 52 i6, p. A343, American Diabetes Association (June 2003).	
	R33	TRISCARI, J. <i>et al.</i> , "Multiple Ascending Doses of CS-917, a Novel Fructose 1,6-Bisphosphatase (FBPase) Inhibitor, in Subjects with Type 2 Diabetes Treated for 14 Days" poster presented at The American Diabetes Association 66 th Scientific Session, Washington, DC (June 2006).	
	R34	TURNBULL, A. <i>et al.</i> , "Pharmacological inhibition of glycogen phosphorylase (GP) lowers plasma glucose in rat models of type 2 diabetes. (Integrated Physiology—Liver 1485-P)," <i>Diabetes</i> , Vol. 52 i6, p. A343, American Diabetes Association (June 2003).	
	R35	TURNER, R.C. <i>et al.</i> , "U.K. Prospective Diabetes Study 16: Overview of 6 Years' Therapy of Type II Diabetes, a Progressive Disease. (U.K. Prospective Diabetes Study Group)" <i>Diabetes</i> 44(11):1249(10) American Diabetes Association (Nov. 1995).	
	R36	UNGER, R. H. "How Obesity Causes Diabetes in Zucker Diabetic Fatty Rats" <i>Trends Endocrinol Metab</i> 7: 276-282 Elsevier Science Inc. (1998).	
	R37	VAN POELJE, P.D. <i>et al.</i> , "Characterization of the Mechanism of Action and Antidiabetic Activity of MB06322, a Potent and Selective Inhibitor of Fructose 1,6-Bisphosphatase" <i>DIAEAZ</i> 52(2): A366, Journal of the American Diabetes Association Abstract No. 1523-P, American Diabetes Association (June 2004).	
	R38	VAN POELJE, P.D., <i>et al.</i> , "Comparative Metabolic Effects of a Novel Fructose 1,6-Bisphosphatase Inhibitor and Metformin in the Female ZDF Rat", Abstracts of the 41 st Annual Meeting of The European Association for the Study of Diabetes, Athens, Greece <i>Diabetologia</i> 48(1):A278 Abstract No. 765 Springer-Verlag (August 2005).	
	R39	VAN POELJE, P.D. <i>et al.</i> , "Inhibition of Fructose 1,6-Bisphosphatase Reduces Excessive Endogenous Glucose Production and Attenuates Hyperglycemia in Zucker Diabetic Fatty Rats" <i>Diabetes</i> 55:1747-1754, American Diabetes Association (June 2006).	

Examiner Signature	Date Considered
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Complete if Known

Application Number	09/900,364
Filing Date	July 5, 2001
First Named Inventor	Paul D. van Poelje
Group Art Unit	1617
Examiner Name	Leonard M. Williams
Attorney Docket Number	MET-037CXT

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	R40	VAN POELJE, P.D. <i>et al.</i> , "MB06322 (CS-917) Lowers Blood Glucose in Rodents by Inhibiting Both Hepatic and Renal Gluconeogenesis" <i>DIAEAZ</i> 55(1): A137, Journal of the American Diabetes Association Abstract No. 575-P, American Diabetes Association (June 2006).	
	R41	VAN POELJE, P.D. <i>et al.</i> , "Fructose 1,6-Bisphosphatase Inhibition Enhances the Antidiabetic Activity of Insulin Sensitizers in the ZDF Rat" <i>DIAEAZ</i> 52(2): A366, Journal of the American Diabetes Association Abstract No. 1524-P, American Diabetes Association (June 2004).	
	R42	VAN POELJE, P.D. "MB06322, a Potent Inhibitor of Gluconeogenesis, Attenuates Hyperglycemia without Causing Weight Gain or Hypoglycemia in Female Zucker Diabetic Fatty Rats" <i>DIAEAZ</i> 54(1):A124, Journal of the American Diabetes Association Abstract No. 503-P, American Diabetes Association (June 2005).	
	R43	WALKER, J. <i>et al.</i> , "Safety and Tolerability of Single Doses of CS-917, a Novel Gluconeogenesis Inhibitor, in Normal Male Volunteers" <i>DIAEAZ</i> 55(1): A463, Journal of the American Diabetes Association Abstract No. 2002-PO, American Diabetes Association (June 2006).	
	R44	WALKER, J. <i>et al.</i> , "Safety, Tolerability and Pharmacodynamics of Multiple Doses of CS-917 in Normal Volunteers" <i>DIAEAZ</i> 55(1): A464, Journal of the American Diabetes Association Abstract No. 2003-PO, American Diabetes Association (June 2006).	
	R45	YOSHIDA, T. <i>et al.</i> , "Comparison of Acute and Chronic Glucose-Lowering Effect of CS-917, a Fructose 1,6-Bisphosphatase (FBPase) Inhibitor, and Metformin in Rat Models of Type 2 Diabetes" poster presented at The American Diabetes Association 66 th Scientific Session, Washington, DC (June 2006).	
	R46	YOSHIDA, T. <i>et al.</i> , "CS-917, a Fructose 1,6-Bisphosphatase Inhibitor, Has Glucose-Lowering Effects in Cynomolgus Monkeys and Improves Postprandial Hyperglycemia in Goto-Kakizaki (GK) Rats" <i>DIAEAZ</i> 54(1): A116-A117, Journal of the American Diabetes Association Abstract No. 472-P, American Diabetes Association (June 2005).	
	R47		
	R48		

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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